

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,

20-cr-163 (PKC)

-against-

OPINION AND ORDER

LOUIS GRASSO, et al,

Defendants.

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CASTEL, U.S.D.J.

Defendants in this case are racehorse trainers, a racehorse-product supplier and a veterinarian that are charged with violating the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, et seq. (the “FDCA”). The fourth superseding indictment (the “Indictment” (Doc 79)) alleges that the defendants and others orchestrated a scheme to manufacture, distribute and receive adulterated and misbranded performance-enhancing drugs (“PEDs”) and secretly administer those PEDs to racehorses. (Indictment ¶ 2.) Defendants now move to dismiss the Indictment, and, alternatively, seek a bill of particulars.

BACKGROUND

Professional horse racing enjoys a robust following in the United States and abroad, and the horse racing industry accounts for billions of dollars in horse sales, race bets, competition purses, and related commercial activity. The horse racing industry is also subject to various state and federal regulations. In this case, the defendants are accused of orchestrating a scheme to provide PEDs to racehorses and conspiring to defraud and mislead “government

agencies, including federal and state drug regulators, various state horse racing regulators, and the betting public” by concealing the use of PEDs from them. (Id. ¶ 4.) The Indictment alleges that the goal of the scheme, in part, was for participating horse trainers to profit by improving their horses’ racing records, which increases their share of the horses’ winnings and yields higher trainer fees. (Id. ¶ 2.)

The Indictment charges all defendants with a single count of Drug Adulteration and Misbranding Conspiracy under the FDCA, 21 U.S.C. §§ 331, 333. It further alleges that veterinarians participating in the scheme, including defendant Louis Grasso, wrote invalid prescriptions – including by submitting prescriptions for “purported canine patients” – for thousands of units of PEDs which were then filled by pharmacies. (Id. ¶¶ 2, 12.) The scheme participants allegedly “manufactured, purchased, sold, shipped, delivered, received and administered [to horses]” these PEDs issued pursuant to invalid prescriptions. (Id. ¶ 2.) The participants also allegedly customized certain PEDs for use on racehorses. (Id.)

The Indictment alleges that from at least 2015 through 2020, defendants conspired to commit the charged offense under the FDCA. The Indictment asserts that from at least 2017 through at least 2020, defendant Grasso was a veterinarian licensed in New York and New Jersey, and that he supplied adulterated and misbranded PEDs to trainers across the United States, including in New York, and that he manufactured and distributed customized PEDs. (Id. ¶ 9.) Defendant Polisenio is alleged to have obtained PEDs from Grasso for use in his veterinary-supply business. (Id. ¶ 10.) Defendants Guida, Banca and Allard are horse trainers who allegedly obtained adulterated and misbranded PEDs from defendant Grasso and administered them to horses. (Id. ¶ 11.) The Indictment alleges various overt acts of the conspiracy, such as causing a prescription to be filled at a Texas pharmacy using an invalid veterinary license with

the goal of using the prescription at a facility in this District, defendant Grasso's advising on the administration of misbranded and adulterated PEDs, and certain defendants' requesting and obtaining PEDs from defendant Grasso. (Id. ¶ 18.) It alleges that the scheme participants defrauded and misled "government agencies, including federal and state drug regulators, various state horse racing regulators, and the betting public." (Id. ¶ 4.)

As described in the government's memorandum in opposition to the motion, the present case grew out of a related investigation that resulted in the indictment of nineteen defendants in United States v. Jorge Navarro, et al., 20 Cr. 160 (MKV). The sixth superseding indictment in that case includes four counts of misbranding conspiracy under the FDCA and, as to three defendants, one count of mail and wire fraud conspiracy. (Id. at Doc 283.) The government represents that in conducting the Navarro investigation, it learned that veterinarians and trainers were conspiring to use PEDs that evaded detection under anti-doping protocols. (Opp. Mem. at 6.) On July 30, 2021, Judge Vyskocil denied a motion to dismiss the indictment on grounds similar to those raised in the present motion to dismiss. United States v. Navarro, 2021 WL 3271803 (S.D.N.Y. July 30, 2021).

## DISCUSSION

The single count of the Indictment charges a drug adulteration and misbranding conspiracy in professional horse racing from at least 2017 through at least February 2020. The count runs 15 pages in length with the objects of the conspiracy described in five paragraphs (Indictment ¶¶ 13–17) and sixteen overt acts are alleged (Id. ¶¶ 18(a)–(p)).

Defendants challenge the Indictment principally on two grounds. First, they assert that the statute charged as an object of the conspiracy does not place them on fair notice of

conduct violative thereof. They assert that the felony object of the conspiracy requires an allegation that the defendants acted with the intent to defraud a consumer or a consumer protection agency, such as the Food and Drug Administration (“FDA”). The Indictment is defective and overbroad, they urge, because it alleges an intent to defraud “government agencies, including federal and state drug regulators, various state horse racing regulators, and the betting public.” In the alternative, defendants seek a bill of particulars on this issue. Second, they assert that the Supreme Court’s grant of a writ of certiorari and remand to the Third Circuit in Murray Rojas v. United States, 21-1504 (Order of Nov. 1, 2021)(summary disposition) should be read to mean that the direct administration of drugs obtained from a veterinarian without a prescription is not within the scope of the FDCA and the Indictment, therefore, sweeps in lawful conduct.

The Court will address each argument in turn and begins with a discussion of the standards on a motion to dismiss an indictment.

A. Legal Standard for a Motion to Dismiss an Indictment.

The Federal Rules of Criminal Procedure require an indictment to be “a plain, concise and definite written statement of the essential facts constituting the offense charged.” Fed. R. Crim. P. 7(c). The Rules permit the dismissal of a criminal indictment where the indictment “fail[s] to state an offense.” Fed. R. Crim. P. 12(b)(3)(B)(v). “Since federal crimes are ‘solely creatures of statute,’ a federal indictment can be challenged on the ground that it fails to allege a crime within the terms of the applicable statute.” United States v. Aleynikov, 676 F.3d 71, 75–76 (2d Cir. 2012) (citing Dowling v. United States, 473 U.S. 207, 213 (1985); United States v. Pirro, 212 F.3d 86, 91–92 (2d Cir. 2000)). Indeed, “a criminal defendant is entitled to an indictment that states the essential elements of the charge against him.” Pirro, 212

F.3d at 91 (citing Jones v. United States, 526 U.S. 227, 232 (1999)). A court considering a motion to dismiss an indictment accepts the indictment’s allegations as true and does not consider the sufficiency of the evidence that the government is likely to offer at trial. United States v. Perez, 575 F.3d 164, 166 (2d Cir. 2009).

Generally, “an indictment need ‘do little more than to track the language of the statute charged and state the time and place (in approximate terms) of the alleged crime.’” United States v. Stringer, 730 F.3d 120, 124 (2d Cir. 2013) (quoting Pirro, 212 F.3d at 92). A sufficient indictment need only “contain[] the elements of the offense charged and fairly inform[] a defendant of the charge against which he must defend” and “enable[] [a defendant] to plead an acquittal or conviction in bar of future prosecutions for the same offense.” United States v. Resendiz-Ponce, 549 U.S. 102, 108 (2007); In re Terrorist Bombings of U.S. Embassies in E. Africa, 552 F.3d 93, 150 (2d Cir. 2008). “An indictment . . . need not be perfect, and common sense and reason are more important than technicalities.” United States v. De La Pava, 268 F.3d 157, 162 (2d Cir. 2001).

**B. The Indictment Properly Alleges the Object of the Fraud,  
But the Court Will Require a Bill of Particulars.**

The FDCA declares certain acts to be violations, including the adulteration or misbranding of a drug, the introduction into interstate commerce of any drug that is adulterated or misbranded, and the mutilation or removal of labeling under specified circumstances. 21 U.S.C. §§ 333(a), (b) & (k). The Indictment charges each of these violations as an object of the conspiracy. (Indictment ¶¶ 14–17.) It further charges that each of these violations was committed with an “intent to defraud or mislead,” thereby rendering the object offenses to be felonies. (Id.); 21 U.S.C. § 333(a)(2). Specifically, the Indictment alleges that members of the

conspiracy “routinely attempted to deceive and mislead government agencies, including federal and state drug and horseracing regulators, pharmacies, and the betting public.” (Indictment ¶ 16.)

The defendants argue that because the statute was intended to protect the consuming public, only consumers or consumer protection agencies may be the target of the intent to defraud or mislead under section 333(a)(2) and, therefore, the Indictment does not allege a proper “victim” and should be dismissed. Notably, the felony-enhancement provision does not state who must be the target of the “intent to defraud or mislead.” Alternatively, defendants argue that the statute did not give them fair notice of the conduct that would fall under the felony enhancement under section 333(a)(2) and the Indictment fails to give them fair notice of the intended targets who they are alleged to have intended to deceive.

This Court adopts the thorough and well-reasoned analysis of Judge Vyskocil in United States v. Navarro, 20 Cr. 00160 (MKV), 2021 WL 3271803 (S.D.N.Y. July 30, 2021), and concludes that racing authorities and state and federal drug regulatory agencies, including the FDA, may be the objects of the intent to defraud or mislead. This Court agrees that misleading third parties, including racing officials and government agencies not in the business of consumer protection, in order to avoid detection by consumers and consumer protection agencies is tantamount to misleading consumers. In light of Navarro, the Court need only be brief.

Second Circuit precedent undermines defendants’ argument and supports the conclusion in Navarro. In United States v. Milstein, the defendant argued that his conviction under section 333(a)(2) should not stand because the trial judge’s instruction permitted the jury to convict based upon an intent to defraud the purchasing public and government agencies. 401 F.3d 53, 70 (2d Cir. 2005). The Court affirmed the conviction finding the reasoning of the Tenth

Circuit to be persuasive that government agencies could be the target of the intent to defraud because misleading the agencies frustrated their ability to protect consumers. Id. (citing United States v. Mitcheltree, 940 F.2d 1329, 1347–50 (10th Cir.1991)).<sup>1</sup>

Defendants endeavor to cabin Milstein to an instance in which there is a direct intent to defraud the purchasing public or consumer protection agencies. But the scheme in Milstein involved purchasing drugs intended for consumption outside the United States, relabeling them with forged labels and selling them to doctors, pharmacists and pharmaceutical wholesalers. Id. at 59. None of the foregoing were consumers or consumer protection agencies. Instead, the Milstein Court adopted the Tenth Circuit’s “indirectly misled and defrauded the public” standard. Milstein, 401 F.3d at 69 (quoting Mitcheltree 940 F.3d at 1346). Milstein also rejected Fifth and Sixth Amendment claims that the defendant had no notice that his conduct violated the statute, concluding that he was on notice that deceiving parties in the chain of distribution could amount to deceiving government agencies and the consuming public. Milstein, 401 F.3d at 69–70.

Here, as in Navarro, the principles set forth in Milstein apply. The allegation that defendants intended to defraud or mislead “government agencies, including federal and state drug regulators, various state horse racing regulators, and the betting public” adequately alleges the targets of the intent to defraud. Moreover, the Indictment appropriately and sufficiently tracks the language of the relevant statutes and provides a “plain, concise and definite” statement

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<sup>1</sup> See also United States v. Orrego-Martinez, 575 F.3d 1, 7 (1st Cir. 2009) (“The elements of a [§ 333(a)(2)] violation are (1) a violation of § 331, (2) committed by ... someone “with the intent to defraud or mislead. The prosecution must prove beyond a reasonable doubt that a defendant intended to defraud or mislead someone, but the indictment need not specify the intended victim; the focus is on defendant's intent, not the victim's identity.”) (quoting United States v. Arlen, 947 F.2d 139, 145 (5th Cir. 1991).)

of the charge. For these reasons, defendants' motion to dismiss the indictment for failure to properly allege the object of the fraud is denied.

Defendants also urge that the vagueness with which the Indictment describes the persons or entities that defendants purportedly intended to defraud entitles them to a bill of particulars. At the November 22, 2021 pretrial conference, the Court reserved decision on the defendants' request for a bill of particulars that identifies the government agencies and federal and state drug regulators that were the objects of the intent to defraud. (See Minute Entry for Nov. 21, 2021.)

Rule 7(f), Fed. R. Crim. P., allows a defendant to move for a bill of particulars. The purpose of a bill of particulars is to “enable[e] defendant to prepare for trial, to prevent surprise, and to interpose a plea of double jeopardy should he be prosecuted a second time for the same offense.” United States v. Bortnovsky, 820 F.2d 572, 574 (2d Cir. 1987). “A bill of particulars is required only where the charges of the indictment are so general that they do not advise the defendant of the specific acts of which he is accused.” United States v. Walsh, 194 F.3d 37, 47 (2d Cir. 1999). “[A] bill of particulars is not necessary where the government has made sufficient disclosures concerning its evidence and witnesses by other means.” Id. “The decision of whether or not to grant a bill of particulars rests within the sound direction of the district court.” Bortnovsky, 820 F.2d at 574.

The Indictment in this case alleges that defendants “routinely defrauded and misled government agencies, including federal and state drug regulators, various state horse racing regulators, and the betting public” – but it makes no reference to which particular “government agencies,” “federal and state drug regulators,” or “various state horse racing regulators” were defrauded. (Indictment ¶ 4.) As defendants note in their memorandum, “there



are a host of different agencies that the indictment can be referring to” such as “the Drug Enforcement Agency, the Department of Health and Human Services, the Center of Medicare and Medicaid-Services, the Center for Disease Control and Prevention, Customs and Border Patrol, the Federal Drug Administration, among others[.]” (Def.’s Mem. at 9.)

The Court will grant defendants’ request for a bill of particulars related to the target of the intent to mislead or defraud (*i.e.*, which “government agencies,” “horse racing regulators” or “federal and state drug regulators” defendants allegedly intended to mislead or defraud). Indeed, the information sought regarding the particular “government agencies,” “horse racing regulators” and “federal and state drug regulators” permits defendants to defend against the charge.

Footnote 10 in the government’s memorandum in opposition to the motion exemplifies the need for a bill of particulars in this case. In footnote 10, the government notes that “[h]ere, U.S. Customs and foreign customs authorities are among those misled through the activities of these defendants, who moved misbranded and adulterated drugs across the [Canadian] border” and cites to paragraph 18(k) of the Indictment for support. But in the entire Indictment there is no mention of U.S. Customs and Border Patrol, it does not describe smuggling over the Canadian border, and paragraph 18(k) alleges only that “GRASSO agreed . . . to provide Flynn with pre-printed labels to be applied to otherwise unlabeled bottles of PEDs.” The closest the Indictment comes to even hinting at the relevance of U.S. Customs and Border Patrol or Canadian border authorities is in paragraph 18(c) which alleges only that “ALLARD sent GRASSO a text message, stating: ‘I will need 3 bottles of Red Acid to go to Canada Thursday’.” Granting the bill of particulars will avoid the need for defendants to guess which of

the various potential unnamed government agencies they are alleged to have intended to defraud or mislead.

For these reasons, the government shall provide to the defendants a bill of particulars that identifies the ultimate targets and indirect targets of the intent to defraud or mislead.

C. The Indictment Alleges a Misbranding Offense Within the Scope of the FDCA.

Based on the admission of error by the Solicitor General in her brief on the appeal of Murray Rojas v. United States, (Doc 158, Ex. 2 (“SG Brief”)), the defendants assert that the direct administration of drugs obtained from a veterinarian without a prescription is not within the scope of the FDCA.

To briefly summarize, in Rojas the defendant was convicted of a “misbranding” offense under the FDCA, and that conviction was affirmed by the Third Circuit. (SG Brief at 7–8). The defendant brought a petition for a writ of certiorari, contending that “the FDCA’s restrictions on ‘dispensing’ prescription animal drugs do not encompass the ‘administering’ of such drugs directly by a veterinarian to an animal.” (Id. at 7.) In response, the Solicitor General filed a brief in which she agreed that “a veterinarian’s direct injection of animal drugs without a written or oral order in the course of her professional practice cannot provide the basis of a misbranding conviction” under the FDCA. (Id.) The brief “acknowledge[d] that a veterinarian who personally injects a drug into an animal under her direct care in the course of her professional practice, without first issuing a written or oral order, has not engaged in misbranding under the FDCA.” (Id. at 10.) The Solicitor General described the requirements of the statutory text as follows:

“The plain text of that provision indicates that an animal drug may lawfully be dispensed via two different methods: either “by . . . a licensed veterinarian . . . in the course of the veterinarian’s professional practice” or “upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian’s professional practice.” Ibid. Therefore, if a veterinarian follows the first method and personally dispenses a covered animal drug in the course of the veterinarian’s professional practice, no written or oral order is required.” (Id.)

The Solicitor General recommended a vacatur of the court of appeals’ judgment and a remand for further proceedings. (Id.) The Supreme Court granted certiorari, vacated the Third Circuit’s ruling and remanded the case. Murray Rojas v. United States, 21-1504 (Order of Nov. 1, 2021) (summary disposition).

Defendants in the present case contend that the vacatur in Rojas means that “felony misbranding cases of the type that the Government is pursuing here need to confine themselves to the commercial conduct of ‘dispensing’ drugs, not the medical action of ‘administering’ them.” (Doc 158 at 2.) But this overstates the reasoning behind the vacatur of Rojas. Indeed, the Solicitor General’s brief in Rojas supports the principle that the direct administration of drugs to an animal by a veterinarian *can* support a misbranding charge under the FDCA where (1) the administration is *not* pursuant to a valid written or oral order *and* (2) the administration is *not* within the veterinarian’s ordinary course of professional practice. (See SG Brief at 10.) Suggesting that Rojas does away with all misbranding offenses based on direct “administration” to the animal by a veterinarian is an incorrect reading of the Solicitor General’s admission of error. (See, e.g., id. at 7, 13).

Several provisions of the Indictment in this case contemplate FDCA misbranding charges on the basis of “administering” drugs to animals. (See, e.g., Indictment ¶ 2 (“The charges in this Indictment result from a scheme orchestrated by LOUIS GRASSO, the defendant, and others . . . to secretly administer . . . PEDs to racehorses . . . ”); ¶ 3 (“By failing to abide by

such proscriptions, racehorse trainers, veterinarians, and others imperil the health and well-being of racehorses by: (1) administering to racehorses unapproved drugs whose chemical composition is unknown . . .”); ¶ 4 (“To avoid detection of their administration of misbranded and adulterated PEDs to racehorses . . . the scheme participants . . .”); ¶ 7 (“During the course of the scheme, LOUIS GRASSO . . . administered the following . . .”). Defendants contend that these provisions of the Indictment fail to allege a crime under the FDCA because they purport to charge a crime based on a veterinarian’s administration of a drug without a prescription directly to an animal during the ordinary course of the veterinarian’s professional practice.

But the Indictment at paragraph 6 limits the type of “administering” that is charged as a crime:

“Pursuant to the FDCA and related regulations, a drug may be deemed “misbranded” or “adulterated” for several reasons, including: . . . (2) if a drug requiring a prescription is administered without a valid prescription, that is, not in the usual course of a veterinarian’s professional practice, or not administered pursuant to any prescription at all[.]”

The Indictment thus charges a misbranding offense where “a drug requiring a prescription is administered without a valid prescription, that is, not in the usual course of a veterinarian’s professional practice[.]” This provision appropriately carves out from the misbranding offense the administration of drugs to animals by a veterinarian without an oral or written order but within the usual course of a veterinarian’s practice. Thus, the Indictment properly “allege[s] a crime within the terms of the applicable statute.” Aleynikov, 676 F.3d at 75–76.

The Indictment does not purport to charge defendants with administering drugs without a prescription but within the ordinary course of veterinary practice. Rather, the Indictment brings a “misbranding” charge based on, for example, “administration of customized PEDs designed and intended to be difficult or impossible to detect in anti-PED tests” (Ind. ¶ 4.);

“shipp[ing] from . . . New York to . . . New Jersey, a package of PEDs, including snake venom and ‘Bronk,’ along with a false prescription made out by GRASSO for a non-existent dog named ‘Butch’ ” (Id. ¶ 18(1)); and “submit[ting] prescriptions to pharmacies under the names and patient files of purported canine patients, in order to disguise the fact that the PEDs, including Epogen and other prescription blood builders, were in fact being obtained for illicit administration to racehorses.” (Id. ¶ 12.) Taking these allegations as true, as is required on a motion to dismiss, a reasonable jury could conclude that administering customized performance enhancing drugs designed to avoid detection in drug testing, or shipping performance enhancing drugs prescribed for a fake dog to be administered by a co-defendant to a horse, is the administration of a drug *not within* the usual course of professional veterinary practice.

Finally, in Rojas the defendant was prejudiced because “the district court’s pre- and post-trial orders are premised on an interpretation of the FDCA under which a veterinarian’s personal injection of drugs without an oral or written order, in the course of her professional practice, can provide the basis for a misbranding conviction.” SG Brief at 12. The district court erred on the same grounds “[w]hen instructing the jury.” Id. Here, on the other hand, neither party contends that any of the Court’s orders have been tainted by reliance on an improper FDCA standard. Even if the Indictment could be interpreted as potentially punishing conduct outside the scope of the FDCA, the appropriate remedy exists in a proper instruction to the jury. While broadening of an indictment through a jury charge may result in an impermissible constructive amendment or variance of the indictment, narrowing of an indictment through a jury charge is permissible. See United States v. Salmonese, 352 F.3d 608, 620 (2d Cir. 2003). In this case, the Court’s evidentiary rulings and instructions to the jury are enlightened by Rojas. Thus,

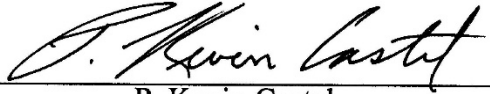
there is no reason for the Court to dismiss the Indictment instead of appropriately instructing the jury on the limitations of the “administering” aspect of the charge.

For these reasons, defendants’ motion to dismiss the Indictment on the basis of the vacatur in Rojas is denied.

#### CONCLUSION

Defendants’ motion to dismiss the Indictment is DENIED. Defendants’ motion for a bill of particulars is GRANTED to the extent indicated herein and shall be provided to defendants within 14 days. The Clerk is respectfully directed to terminate Docs 129 and 158.

SO ORDERED.

  
P. Kevin Castel  
United States District Judge

Dated: New York, New York  
February 9, 2022